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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/988,494      | 11/20/2001  | Tianmei Ouyang       | LIFE040             | 8555             |

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EXAMINER

DAVIS, RUTH A

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/988,494

Applicant(s)

OUYANG ET AL.

Examiner

Ruth A. Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 March 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 11-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group I, claims 1 – 10 in Paper No. 5 is acknowledged. The traversal is on the grounds that there is not a serious burden on examiner and the groups should therefore be examined together. This is not found persuasive because as indicated by separate classification, the groups are separate and distinct, which is sufficient to establish serious burden on examiner.

The requirement is still deemed proper and is therefore made FINAL.

Claims 11 – 32 are withdrawn as being drawn to non-elected subject matter. Claims 1 – 10 have been examined on the merits.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 2 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is drawn to a composition, however is rendered vague and indefinite for reciting “FAD” without first writing out the complete term followed by the abbreviation in parenthesis.

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Claim 7 is drawn to a composition, however is rendered vague and indefinite for reciting "PES" without first writing out the complete term followed by the abbreviation in parenthesis.

In claim 7 line 1, "said phenazine compound" lacks sufficient antecedent basis.

Applicant may prefer to replace "compound" with the term "agent" to more clearly claim the invention.

*Claim Rejections - 35 USC § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1 – 2 and 4 – 10 are rejected under 35 U.S.C. 102(a) as being anticipated by Ouyang et al. (EP 1130111 A2).

Applicant claims a reagent composition comprising a tetrazolium dye, phenazine electron transfer agent and a Group IIIA compound and/or a flavin stabilizing agent. The flavin stabilizing agent is FAD, the phenazine agent is PES, and the composition is dry or wet. The composition further contains an analyte oxidizing signal producing system, comprising an analyte oxidase or dehydrogenase; and an enzyme cofactor.

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Quyang teaches a reagent composition comprising a tetrazolium dye, FAD (coenzyme factor), oxidases and/or dehydrogenases and PES (p.4 – 5). The composition is wet or dry (p.5 0036).

The reference anticipates the claimed subject matter.

6. Claims 1 – 2, 4 – 5 and 8 – 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Nippon Chemiphar Co (Derwent 1985-070861).

Applicant claims a reagent composition comprising a tetrazolium dye, phenazine electron transfer agent and a Group IIIA compound and/or a flavin stabilizing agent. The flavin stabilizing agent is FAD, and the composition is a fluid. The composition further contains an analyte oxidizing signal producing system, comprising an analyte oxidase; and an enzyme cofactor.

Nippon teaches a liquid reagent composition comprising tetrazolium salts, PMS (phenazine electron transfer agent), FAD, and analyte oxidases (abstract).

The reference anticipates the claimed subject matter.

7. Claims 1, 3 – 4, 6 and 8 – 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Geisler et al. (US 4613569).

Applicant claims a reagent composition comprising a tetrazolium dye, phenazine electron transfer agent and a Group IIIA compound and/or a flavin stabilizing agent. The Group IIIA agent is borate or boric acid, and the composition is dry or wet. The composition further

contains an analyte oxidizing signal producing system, comprising an analyte dehydrogenase; and an enzyme cofactor.

Geisler teaches fluid and powder reagent compositions comprising tetrazolium salts, boric acid, dehydrogenases and NAD (enzyme cofactor) (col.1-4).

The reference anticipates the claimed subject matter.

8. Claims 1 – 2, 4, 6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Steinbach et al. (US 4724204).

Applicant claims a reagent composition comprising a tetrazolium dye, phenazine electron transfer agent and a Group IIIA compound and/or a flavin stabilizing agent. The flavin stabilizing agent is FAD; and the composition further contains an analyte oxidizing signal producing system, comprising an analyte dehydrogenase; and an enzyme cofactor.

Steinbach teaches reagent compositions comprising tetrazolium salts (col.4 line 44-59), PMS (phenazine electron transfer agent) (col.6 line 28-30), FAD (col.4 line 28-33), diaphorase (dehydrogenases) (col.6 line 28-30, col.3 line 22-28), and NAD (enzyme cofactor) (col.4 line 28-32).

The reference anticipates the claimed subject matter.

### ***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1 – 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nippon and Geisler.

Applicant claims a fluid or dry reagent composition comprising a tetrazolium dye, phenazine electron transfer agent and a Group IIIA compound and/or a flavin stabilizing agent. The phenazine agent is PES, the flavin stabilizing agent is FAD and the Group IIIA compound is borate or boric acid. The composition further contains an analyte oxidizing signal producing system, comprising an analyte oxidase or dehydrogenase; and an enzyme cofactor.

Nippon teaches a liquid reagent composition for diagnostic use, the composition comprising tetrazolium salts, PMS (phenazine electron transfer agent), FAD, and analyte oxidases (abstract).

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Geisler teaches fluid and powder reagent compositions for diagnostic use, the compositions comprising tetrazolium salts, boric acid, dehydrogenases and NAD (enzyme cofactor) (col.1-4).

The references do not teach the reagent compositions wherein both a Group IIIA compound and a flavin stabilizing agent are used. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the diagnostic reagents for their common use, as disclosed by the cited references above. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated to combine the instant ingredients with a reasonable expectation for successfully obtaining an effective reagent composition. Although the references do not teach PES as the phenazine agent, it would have been well within the purview of one of ordinary skill in the art to use PES in the reagent composition obtained by the combined teachings, because it was a well known phenazine electron transferring agent (as evidenced by Ouyang et al.).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 703-308-6310. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

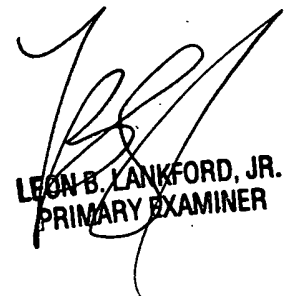
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-0196. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.



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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ruth A. Davis; rad  
May 16, 2003



LEON B. LANKFORD, JR.  
PRIMARY EXAMINER